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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/073,307	02/13/2002	Hartmut Strobel	04734.0004	4483

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EXAMINER

RAO, DEEPAK R

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 03/20/2003

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
10/073,307

Applicant(s)
Strobel et al.

Examiner
Deepak Rao

Art Unit
1624



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Feb 13, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 ☒ are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 6-20 ☒ are rejected.
- 7) ☒ Claim(s) 5 is/~~are~~ objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4 6) ☐ Other:

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DETAILED ACTION

Claims 1-20 are pending in this application.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12-16 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

1. Claims 12-16 are drawn to “The method of treating in a mammal....” and refer to claims 6-10 only for the compound as defined in those claims, which does not appear to be properly dependent. The dependent claims do not link to the method of the base claims.
2. In claims 12-16, many of the stated diseases are unclear and confusing. It is not clear what is intended by “diabetes complications” - the specification provides ‘nephropathy, retinopathy’ as examples (see page 47, line 16) of the same, however, the above terms are already present in the claims and therefore, it is not clear what ‘other’ complications are intended by the above recitation.
3. Claims 12-16 are drawn to ‘the method of treating in a mammal a disease....’ following which, the listed diseases “restricted memory performance or a restricted ability to learn”

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are not clear. The specification does not provide any help in explaining the treatment of the above.

4. In claim 20, it is not clear what is intended by "appropriate acid or acid chloride". The specification on page 27 does not provide any help.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-4, 6-9, 11-15 and 17-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Beasley et al., WO 97/04775. The instantly claimed compounds read on reference disclosed compounds, see formula (I) in page 4 and the species of Examples 5 and 6. The reference discloses that the compounds have therapeutic effect on various diseases of mammal, including asthma, diabetes insipidus, stroke, etc. (see page 7, starting at line lines 23). The instant claims 6-9, 11-15 and 17 read on the prior art taught therapeutic effect because the instant claims are drawn to administration of the prior art compounds, in same dosages, to the same population. The therapeutic effect of claims 6-9 is evident from the dependent claim 12-15. The prior art also teaches that the compounds are useful in the treatment of the instantly claimed

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diseases and therefore, the instantly claimed mechanism of stimulating the expression of endothelial NO-synthase is inherently taught in the reference.

2. Claims 1, 18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Niewoehner et al., EP 253257. The instantly claimed compounds read on reference disclosed compounds, see compounds 18 and 21 in Table 1 (page 14).

3. Claims 6-9, 11-15 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Horn et al., EP 420064. The reference discloses 2-amidotetralin derivatives (see formula in page 3 wherein R_4 is aryl and the compounds of Examples 3 and 14) and the reference discloses that the compounds have therapeutic effect on various diseases of mammal, including sexual dysfunction, etc. (see page 5, lines 6-22). The instant claims read on the prior art taught therapeutic effect because the instant claims are drawn to administration of the prior art compounds, in same dosages, to the same population. The therapeutic effect of claims 6-9 is evident from the dependent claims 12-15. The prior art also teaches that the compounds are useful in the treatment of the instantly claimed disease of erectile dysfunction and therefore, the instantly claimed mechanism of stimulating the expression of endothelial NO-synthase is inherently taught in the reference.

4. Claims 6-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Horn et al., EP 420064. The reference discloses amide compounds (see formula (I) in page 2 and the species of Example 6) and the reference discloses that the compounds have therapeutic effect on various diseases, including stroke, etc. (see page 1, lines 18+). The instant claims read on the prior art

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taught therapeutic effect because the instant claims are drawn to administration of the prior art compounds, in same dosages, to the same population. The therapeutic effect of claims 6-10 is evident from the dependent claims 12-16. The prior art also teaches that the compounds are useful in the treatment of the instantly claimed disease of stroke, etc. and therefore, the instantly claimed mechanism of stimulating the expression of endothelial NO-synthase is inherently taught in the reference.

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 1 and 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Albrecht et al., Chem. Abstract 77:88182. The reference teaches substituted tetrahydronaphthalenyl compounds having a furan attached through an amide linkage, which is structurally analogous to instantly claimed compounds. See the compounds disclosed in the enclosed copy of CAPLUS computer search report. The compounds are taught to be useful as antimicrobial agents, see the abstract. The instant compounds differ from the reference compounds having the amide side chain at a position different from the reference compounds, i.e., the claims require the attachment at 2-position as compared to the reference compounds wherein it is at the 1-position. In other words, the reference teaches 1-substituted tetrahydronaphthalenyl compounds and the instant claims are drawn to 2-substituted compounds. It would have been obvious to one having ordinary skill in the art at the time of the invention to prepare the instantly claimed compounds because they are positional isomers of the reference compounds. One having ordinary skill in the art would have been motivated to prepare the instantly claimed compounds because such isomeric compounds are suggestive of one another and would be expected to share similar properties and therefore, the same use as taught for the reference compounds, i.e., as therapeutic agents. It has been held that a compound which is isomeric with a compound of prior art is *prima facie* obvious absent unexpected results. *In re Finley*, 81 USPQ 383 (CCPA 1949); *In re Norris*, 84 USPQ 458 (CCPA 1950); *In re Dillon*, 919 F.2d at 696, 16 USPQ2d at 1904 (Fed. Cir. 1990).

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Allowable Subject Matter

Claim 5 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The references of record do not teach or fairly suggest the instantly claimed compounds.

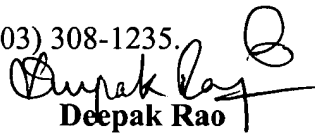
Receipt is acknowledged of the Information Disclosure Statement filed on June 13, 2002 and a copy is enclosed herewith.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (703) 305-1879. The examiner can normally be reached on Tuesday-Friday from 6:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Mukund Shah, can be reached on (703) 308-4716. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


Deepak Rao
Primary Examiner
Art Unit 1624

March 19, 2003